

Translation

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 664044	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2003/012320	International filing date (day/month/year) 26 September 2003 (26.09.2003)	Priority date (day/month/year) 27 September 2002 (27.09.2002)	
International Patent Classification (IPC) or national classification and IPC C07D 473/18, 473/16, 473/24, 473/34, 473/40, A61K 31/522, 31/5377, 31/55, A61P 11/06, 17/00, 31/12, 35/00, 37/02, 37/08, 43/00			
Applicant SUMITOMO PHARMACEUTICALS COMPANY, LIMITED			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 26 April 2004 (26.04.2004)	Date of completion of this report 08 October 2004 (08.10.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/012320

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-46	YES
	Claims		NO
Inventive step (IS)	Claims	5-7, 10, 12, 13, 16-25, 28, 29	YES
	Claims	1-4, 8, 9, 11, 14, 15, 26, 27, 30-46	NO
Industrial applicability (IA)	Claims	1-46	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. WO 99/28321 A1
2. JP 11-193282 A
3. EP 1043021 A1
4. WO 98/01448 A1

I. Claims 1-4, 8, 9, and 11

Document 1 describes a drug that has the compounds represented by General Formula (I) as its active ingredient. The compounds of Examples 39, 40, 45, and 62, which are concrete compounds of General Formula (I), are equivalent to the compounds of General Formula (I) of this application. Furthermore, page 27, lines 16 to 17, lists a transdermal agent, aerosol agent, etc., as dosage forms of the drug. Therefore, persons skilled in the art can easily formulate the compounds of Examples 39, 40, 45, and 62 as a transdermal agent or aerosol agent.

As a result, based on the description in document 1, the inventions of claims 1-4, 8, 9, and 11 lack an inventive step.

II. Claims 14, 15, 26, 27, and 30-46

Document 1 describes the compounds represented by General Formula (I) that are useful as an interferon inducing agent, antiviral agent, anticancer agent, etc., and as concrete compounds it describes those in which R^1 is an alkyl group substituted by a lower alkoxy carbonyl group (Examples 39, 40, 45 and 62).

Document 2 describes compounds represented by General Formula (I) that have chemical structures similar to those of the compounds described in document 1 and have similar activity. Document 2 lists an alkoxy carbonyl group and also an alkyl carbamoyl group as R^2 (equivalent to R^1 of document 1).

Because it is common practice in the technical field involving chemicals used as drugs for persons skilled in the art to modify terminal substituents and obtain compounds that are optimal or preferable as drugs, this examination finds that persons skilled in the art can easily conceive of using an alkenyl group, etc., in place of the alkyl group moiety and replacing the oxycarbonyl group with a carbamoyl group, etc., in the compounds described in document 1.

Furthermore, this examination finds that the compounds of claims 14 and 15 of this application do not provide any particular outstanding effect in comparison with the compounds described in document 1.

As a result, based on the descriptions in documents 1 and 2, the inventions of claims 14, 15, 26, 27, and 30-46 lack an inventive step.

(Continued)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box V:

III. Claims 5-7 and 10

Neither document 1 nor document 2 describes or suggests that when compounds in which the benzyl group at position 9 is replaced by a substituent equivalent to $-Y^2-Q^2$ in the present application are applied topically, they are quickly metabolized and converted to substances with low activity, and this matter is not obvious to persons skilled in the art.

As a result, the inventions of claims 5-7 and 10 of this application are novel and involve an inventive step with respect to documents 1 and 2.

IV. Claims 12, 13, 16-25, 28 and 29

Documents 1-4 neither describe nor suggest the compounds of claims 12, 13, and 16-25 of this application, and these compounds cannot easily be conceived of by persons skilled in the art.

As a result, the inventions of claims 12, 13, 16-25, 28, and 29 of this application are novel and involve an inventive step with respect to documents 1 and 2.